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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,351	07/24/2003	Michael Russell	64371-5003-US	1688

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,351	RUSSELL ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *17-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-16 and 34-35, SEQ ID NO:1 (for claim 3), a polypeptide (for claim 4), a growth factor (for claim 5), and a brain derived neurotrophic factor (BDNF) (for claim 8) in the reply filed on 1/26/07 is acknowledged.

2. Claims 17-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/26/07.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. SEQ ID NO:1 and SEQ ID NO:3 are nucleotide sequences and not amino acid sequences. It is believed that the applicant meant to elect the sequence that SEQ ID NO:1 encodes, which appears to be SEQ ID NO:2. Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

6. Claims 1-2, 4-7, 9, 11-16, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell et al. ("Russell"). Russell teaches a composition of wheat germ agglutinin (WGA) conjugated to nerve growth factor (NGF) that is administered intranasally to rats to increase neuronal cell survival.

7. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. The Russell abstract cited above is the instant applicant's own work. While the abstract clearly states that the applicant had a composition of WGA conjugated to NGF, the examiner has not been able to find any art related to this work that teaches the amino acid sequence of the WGA used in the composition disclosed by Russell.

8. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information: did the WGA used in the composition of the Russell abstract have SEQ ID NO:2 as recited in claim 3?

9. This Office action has a requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the requirement for information. The time period for reply to the requirement coincides with the time period for reply to this Office action.

10. Claims 1-2, 4-7, 9, 11-16, and 34-35 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Michael Russel, Yongjin Hou, and Albert Chu are the authors of the Russell et al. abstract cited in **¶6** above. However, the inventive entity of the instant application is Michael Russel, Yongjin Hou, and Carl Cotman. It is unclear how Carl Cotman is an

inventor of the instant invention in place of Albert Chu, but is not an author of the anticipating prior art of record along with the other two co-authors/co-inventors.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-2, 4-16 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell in view of Curtis et al. The teachings of Russell are as set forth in **¶6** above. Russell does not teach a composition comprising BDNF. Curtis teaches that NGF, BDNF, and WGA are transported retrogradely in neurons (from the nerve terminal, along the axon, to the neuronal cell body), and that nerve injury increases the rate and magnitude of this retrograde transport (abstract, pages 106-107, and Fig. 1). However, the rate and magnitude of this

retrograde transport after nerve injury is much greater for WGA than it is for either NGF or BDNF (retrograde transport more than quadruples for WGA after nerve injury; however, it less than doubles for BDNF after nerve injury, see Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition by conjugating WGA to BDNF in order for the neurotrophic growth factor BDNF be utilized by injured neurons more quickly and in a greater amount in order to rescue as many damaged neurons as is therapeutically possible before neuronal death occurs. The increased ability and capacity for WGA to be retrogradely transported in a greater amount than unconjugated BDNF, and the successful conjugation of WGA to a neurotrophic growth factor (NGF) in the same neurotrophin family as BDNF (BDNF has an endogenous dimer structure and shares the same low-affinity neurotrophin receptor (LNR) with NGF, etc.) as taught by Russell and Curtis, provides a strong motivation and a reasonable expectation of success (because WGA-NGF conjugates are biologically active), thus rendering the instant invention *prima facie* obvious in a clinical setting for the preservation of injured neurons.

14. Claims 1-16 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell in view of Curtis as applied to claims 1-2, 4-16 and 34-35 above, and further in view of Hiraki et al.(WO 00/10382, "Hiraki"). Russell and Curtis do not disclose SEQ ID NO:1 or SEQ ID NO:2. Hiraki discloses SEQ ID NO:1 and SEQ ID NO:2 (pages 1/9 - 3/9) and teaches that WGA cDNA (SEQ ID NO:1) can be used to make transsynaptic tracer proteins (abstract and Figure 1

(page 1/8)). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition by linking the WGA amino acid sequence to the BDNF amino acid sequence in order for the neurotrophic growth factor BDNF be utilized by injured neurons more quickly and in a greater amount in order to rescue as many damaged neurons as is therapeutically possible before neuronal death occurs. The increased ability and capacity for WGA to be retrogradely transported in a greater amount than unconjugated BDNF, and the successful conjugation of WGA to a neurotrophic growth factor (NGF) in the same neurotrophin family as BDNF (BDNF has an endogenous dimer structure and shares the same low-affinity neurotrophin receptor (LNR) with NGF, etc.) as taught by Russell and Curtis, provides a strong motivation and a reasonable expectation of success (because WGA-NGF conjugates are biologically active), thus rendering the instant invention *prima facie* obvious in a clinical setting for the preservation of injured neurons. Further, the disclosure of Hiraki teaches that a specific species of WGA, SEQ ID NO:2, encoded by SEQ ID NO:1, can be successfully used as a transsynaptic transporter protein that can move between interconnected neurons so that a functional nerve network can be exposed to the therapeutic agent linked to the WGA (see Figures 8 and 15). The construction of the WGA fusion protein eliminates the need for chemical conjugation of the separate components of the instant composition, thereby providing motivation for the artisan to combine the references because then an entire preparatory step in the construction of the

instant composition can be eliminated, simplifying the method of making the instant composition.

15. No claim is allowed.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.

SG

Stephen Gucker

March 13, 2007

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER